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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/613,272

07/03/2003

Mark J. Mamula

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27267

7590

08/18/2009

WIGGIN AND DANA LLP

ATTENTION: PATENT DOCKETING

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EXAMINER

CANELLA, KAREN A

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

08/18/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/613,272	<b>Applicant(s)</b> MAMULA, MARK J.	
	<b>Examiner</b> Karen A. Canella	<b>Art Unit</b> 1643	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,10,19-22 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,4,5 and 10 is/are allowed.
- 6) ☒ Claim(s) 19, 21, 25 is/are rejected.
- 7) ☒ Claim(s) 20 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                 | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 11-14, 17, 18, 26 and 28 have been canceled. Claims 1, 2, 4, 5, 10, 19-22 and 25 are pending and under consideration.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19, 21 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Witter (U.S. 5,565,202) as evidenced by Gene Bank Accession No. BAA32580, November 9, 2007.

Claim 19 is drawn in part to providing a viral protein or a fragment thereof to a patient, wherein said viral protein or fragment thereof comprises an aspartic acid residue which has been treated to form an isoaspartic acid residue. Claim 21 embodies the method of claim 19 wherein said treating step comprises exposing said viral protein or fragment thereof to between 1 and 20% carbon dioxide. Claim 25 embodies the method of claim 19 wherein said aspartic acid residue forms part of an amino acid sequence selected from a group including Asn-Gly, Asn-Ser, and Asp-Gly.

Witter discloses a method wherein cells infected with a MDF serotype 2 virus strain are passaged in cell culture under 5% carbon dioxide (column 3, lines 44-50). Witter discloses that immunization of chickens at 1 day of age, including chicks positive with maternal antibodies against MD (column 7, lines 5-7). Witter discloses that the vaccine provides protective efficacy against Marek's disease in chickens (column 7, lines 50-66).

GeneBank Accession Number BAA32580 provides evidence that glycoprotein C of Marek's Disease Serotype 2 comprises Asn-Gly at residues 204-205, Asn-Ser at residues 303-304, and Asp-Gly at residues 281-282 and residues 347-348. Thus it would be inherent in the method of Witter that Glycoprotein C or another protein associated with Marek's Disease serotype 2 would comprise an isoaspartyl residue because the viral proteins contain numerous sites which are susceptible to conversion to isoaspartyl residues and because the culture conditions were carried out under 5% carbon dioxide which was the same as that claimed. Witter

discloses that the passaged virus lost the ability to cause underied lymphoid leukosis in chickens, however this attenuation is directed toward pathogenicity and has no nexus to the immunogenicity of the adminsintered viral proteins.

All other rejections and objections as set forth or maintained in the prior Office action are withdrawn in light of applicant's amendments.

Claims 1, 2, 4, 5, 10 are allowed.

Claims 20 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Karen A Canella/

Primary Examiner, Art Unit 1643